DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 1, 2015

Medical Designs, LLC
Ms. Kristi Vondra
Vice President of Operations
6709 South Minnesota Avenue, Suite 204
Sioux Falls, South Dakota 57108

Re: K143688
Trade/Device Name: Asfora Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 3, 2015
Received: June 4, 2015

Dear Ms. Vondra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143688

K143688

Device Name
Asfora Anterior Cervical Plate (AACP) System

Indications for Use *(Describe)*
The Asfora Anterior Cervical Plate System is intended to provide temporary stabilization to the anterior spine during the development of cervical spine fusions (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoathrosis, and failed previous fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

1. Submission Sponsor

Medical Designs, LLC
6709 S. Minnesota Ave., Suite 204
Sioux Falls, South Dakota 57108

2. Submission Correspondent

Kristi Vondra, Vice President of Operations
Tel: (605) 275-1032
FAX: (605) 335-3734

3. Date Prepared

June 3, 2015

4. Device Identification

Trade/Proprietary Name:	Asfora Anterior Cervical Plate System
Common/Usual Name:	Anterior Cervical Plate System
Classification Name:	Spinal intervertebral body fixation orthosis
Classification Regulation:	21 CFR §888.3060
Product Code:	KWQ
Device Class:	Class II
Classification Panel:	Orthopaedic and Rehabilitation Devices Panel

5. Predicate Devices

Primary: K122497	Asfora Anterior Cervical Plate System
Additional: K030866	Synthes Cervical Spine Locking Plate

6. Device Description

The Asfora Anterior Cervical Plate System is composed of plates of varying lengths to accommodate surgical procedures from one to four levels. The plates are designed for application to the anterior aspect of the cervical spine and have three locking tabs to reduce the potential for screws to back out of the vertebral body. The screws are provided in diameters of 4.0mm (Variable Angle Implant Screw and Fixed Angle Implant Screw) and 4.4mm (Rescue Screw) and lengths of 12mm, 14mm and 16mm.

7. Indication for Use

The Asfora Anterior Cervical Plate System is intended to provide temporary stabilization to the anterior spine during the development of cervical spine fusions (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

8. Comparison to Predicates

No changes have been made to the intended use, Indications for Use, principle of operation or device materials of the cleared primary predicate Asfora Anterior Cervical Plate System. The subject device is identical to the primary predicate device except for the following differences. The additional plate and screw dimensions are substantially equivalent to the additional predicate.

Characteristic	Difference in Subject Device to Primary Predicate
Plate locking mechanism	Locking tabs instead of locking rings
Plate dimensions	• maximum plate width decreased from 19 to 17.5mm (in range of reference predicate) • additional plate lengths at all 4 levels (in range of reference predicate) • lateral hole to hole distance decreased (from 9 to 8.5mm)
Plate pre-bent angle	All plates pre-lordosed with a radius of 190mm
Screw Drive Feature	Square instead of hexalobe
Variable Angle Implant Screws	Added 4.0 x 12mm screw (in range of reference predicate); spherical head to fit plate recess
Variable Angle Rescue Screw	Diameter decreased (5.0 to 4.4mm) and added 4.4 x 12mm screw (in range of reference predicate)
Fixed Angle Screws	Added fixed angle screws (in range of reference predicate); spherical head to fit plate recess and shank to match plate exit hole
Temporary Fixation Screws	Removed from system; Casper Pin Style recommended for ease of use and functionality, but not provided
Extractor Assembly	Square interface instead of hexalobe
Drill Guide	Change in tip geometry to interface with spherical cavity of plate; addition of fixed angle drill guide configuration
Plate Bender	Simplified, off the shelf French bender
Retention Assembly	Nemcomed design; one-piece square driver with thermoplastic insert.
Sterilization Tray	Minor modification to hold redesigned cervical plates, screws and instruments

9. Functional and Safety Testing

Mechanical testing was conducted, in accordance with *Guidance for Industry and FDA Staff: Spinal System 510(k)s* and ASTM F 1717-14 to ensure the device performs according to specification, to verify that the device is able to withstand clinical loading and maintain mechanical integrity, and is suited for its intended purpose. Testing included dynamic compression bending, static compression bending, static torsion, screw insertion torque evaluation and screw retention force evaluation.

10. Conclusion

Medical Designs, LLC considers the Asfora Anterior Cervical Plate System to be equivalent to the predicate Asfora Anterior Cervical Plate System listed above. This conclusion is based upon the device similarities in intended use, Indications for Use, principle of operation, materials and performance testing.